

## **REMARKS/ARGUMENTS**

Claims 1-6 and 21-28 stand rejected by the Examiner as allegedly exceeding the scope of enablement under 35 U.S.C. §112. At page 9 of the Office Action, however, the Examiner indicated that this rejection would not apply to SERMs within the scope of the molecular structure of claim 13, *e.g.*, in claims 13-21. In accordance with the Examiner's suggestion, the claims have been amended to restrict the SERMs to the generic molecular structure that the Examiner indicated would be acceptable, without prejudice to pursuing other structures in related applications or later-filed divisional applications.

Regarding "androgens" and "estrogens", Applicant believes that these terms are very well defined in the art and that numerous examples have been set forth in the body of the specification. This is not merely functional language as the art is aware of the structures of a large number of androgens and estrogens. Indeed, many androgens and estrogens have distinctive 4-ring steroidal structures wherein the A-ring is non- aromatic for the androgens and aromatic for the estrogens. Also, the term "androgen" and "estrogen" has been widely used in patent claims. See the enclosed excerpts from U.S. Patents 7,214,804 and 7,214,381.

In view of the amendments placing structural limitations on the SERMs, and the other remarks herein, it is urged that the amended claims are fully enabled by the specification, and that the enablement rejection should be withdrawn.

Claims 1-6 and 23-28 stand rejected by the Examiner under 35 U.S.C. §112, second paragraph, as allegedly indefinite because of the recitations "derivative" and "derivatives". While applicant does not necessarily agree that these terms do not have a well-known meaning, the amendments that were done in connection with the enablement rejection do not appear to leave any claims that have those terms in them. Accordingly, it appears that the objection to the terms "derivative" and "derivatives" is moot in view of the amendments herein. Accordingly, it is urged that the rejection based on indefinite claim language should be withdrawn.

Claims 1, 3-6 and 13-28 stand rejected as allegedly obvious under 35 U.S.C. §103 over Labrie 5,362,720 and Labrie WO 96/26201 and an alleged admission at page 2 of the specification.

The Examiner alleges that estrogens are known for treating menopausal symptoms and that Labrie '201 sets forth compounds, for the treatment of breast cancer, within the scope of some of Applicant's broader SERM recitations (although Labrie '201 talks about these compounds as "antiestrogens" -- not SERMs). In the carryover paragraph between 12 and 13 of the Office Action, the Examiner alleges that it is *prima facie* obvious to combine the estrogens and antiestrogens of the prior art, given that both are used for the treatment of "estrogen-dependent diseases." The Examiner cites *In re Kerkhoven* for this concept. However, the present situation differs greatly from the situation at issue in *Kerkhoven*. The term "estrogen-dependent diseases" fails to distinguish between menopause (a condition discussed in one of the cited references) which responds favorably to estrogens, while breast cancer (from another reference) is known to respond unfavorably. In *Kerkhoven*, compounds which had been used independently for a given purpose were combined for accomplishing the same purpose. By contrast, menopausal symptoms and breast cancer are not the same disease, and indeed behave in opposite ways in connection with the effect of estrogens. One of skill in the art would not expect a treatment useful against one of the conditions to be useful against the other. Indeed, quite the opposite.

Another distinction over *Kerkhoven* is that the Examiner here seeks to combine two pharmaceuticals whose mechanisms of action are known to be in conflict. Estrogens are known to activate the estrogen receptor, while antiestrogens are known to block the access of estrogens to the estrogen receptor, thus diminishing the activation of the estrogen receptor. One of skill in the art seeking the benefits of estrogens (for whatever disease) would not expect value from the addition of antiestrogens. Conversely, one of skill in the art utilizing antiestrogens (for treatment of whatever disease) would not expect value from the addition of estrogens. In both instances, whatever value is being provided by the antiestrogen would be expected to diminish in the presence of the estrogen and vice-versa.

The situation could not be more different than that addressed by the court in *Kerkhovem*. First, the individual components the Examiner seeks to combine were not used on the same disease but different diseases whose response to estrogens are not only different but opposite. Second, the two components the Examiner seeks to combine are known to act by mechanisms that would be expected to compete with each other.

For all of the foregoing reasons, it is urged that the Examiner's rejection at 35 U.S.C. §103 should be withdrawn.

The Examiner has maintained double patenting rejections of claims 1-6 and 13-28 over claims 1 and 14 of U.S. Patent No. 6,670,346 and claims 1-2, 8-11 and 19-28 of U.S. Patent No. 6,465,445. In prior responses, Applicant has pointed out that the present claims require estrogen whereas the cited references do not. The Examiner has taken the position that because the cited reference's claims utilize the transition term "comprising", that estrogens are not excluded from the reference's claims. However, a prior art reference must affirmatively teach the subject matter that the Examiner applies in the rejection. It is not enough that the prior art simply fails to exclude it. Were it otherwise, a claim to a pharmaceutical composition could be considered double patenting over a mechanical claim to a physical device based on nothing else than the mechanical claim's use of the transition word "comprising" (which would not necessarily exclude the claimed pharmaceutical composition). Such an interpretation gives the word "comprising" a scope of disclosure far beyond what it actually provides for prior art purposes. Accordingly, it is urged that the double patenting rejection should be withdrawn.

While applicant does not believe that the two prior art patents that the Examiner has cited in the double patenting rejections are relevant for the reasons given, Applicant wishes to note that there are other patents and/or patent applications in the same family as U.S. Patents 6,670,346 and 6,465,445. Those additional family members are included among the citations in the Information Disclosure Statement that is being filed herewith.

## CLARIFICATIONS OF PRIOR AMENDMENT

At page 18 of the Amendment applicant mailed on May 30, 2006, the undersigned wrote that "the '201 reference teaches that EM-652.HC1 is an estrogen receptor antagonist . . . ." This was an inadvertently erroneous statement. While the '201 reference teaches that other benzopyran compounds within the scope of the SERM recitations of the present claims are estrogen receptor antagonists, the '201 reference is not believed to discuss the particular specie EM-652.HCl.

It is urged that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

### EXPRESS MAIL CERTIFICATE

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Dorothy Jenkins

Name of Person Mailing Correspondence




Signature

August 7, 2007

Date of Signature

WOG:db

Respectfully submitted,



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